

INFORMATION PAPER

Military Vaccine Agency

28 November 2006

SUBJECT: Rotavirus Virus and Vaccine

1. Purpose: To describe rotavirus and the vaccine to prevent it.

2. Facts.

a. Microbiology. Rotavirus is the most common cause of severe diarrhea among children, resulting in the hospitalization of approximately 55,000 children each year in the United States and the death of over 600,000 children annually worldwide. The incubation period for rotavirus disease is approximately 2 days. The disease is characterized by vomiting and watery diarrhea for 3 - 8 days, and fever and abdominal pain occur frequently. Immunity after infection is incomplete, but repeat infections tend to be less severe than the original infection. A rotavirus has a characteristic wheel-like appearance when viewed by electron microscopy (the name rotavirus is derived from the Latin *rota*, meaning "wheel"). Rotaviruses are nonenveloped, double-shelled viruses. The genome is composed of 11 segments of double-stranded RNA, which code for six structural and five nonstructural proteins. The virus is stable in the environment.

b. Epidemiology. The primary mode of transmission is fecal-oral, although some have reported low titers of virus in respiratory tract secretions and other body fluids. Because the virus is stable in the environment, transmission can occur through ingestion of contaminated water or food and contact with contaminated surfaces. In the United States and other countries with a temperate climate, the disease has a winter seasonal pattern, with annual epidemics occurring from November to April. The highest rates of illness occur among infants and young children, and most children in the United States are infected by 2 years of age. Adults can also be infected, though disease tends to be mild.

c. Vaccine. While it is important that you wash your child's hands, better hygiene and sanitation have not significantly reduced rotavirus disease. A new, recently licensed vaccine is the best way to protect your child against rotavirus disease. The new vaccine, RotaTeq™, marketed by Merck and Company, is a live, oral, vaccine for preventing rotavirus disease, and is the only vaccine approved in the U.S. that can help protect against rotavirus. Rotavirus vaccine will not prevent diarrhea or vomiting caused by other viruses but it is very effective against rotavirus disease. Studies indicate the vaccine will prevent about 74 percent of all rotavirus cases, about 98 percent of severe cases, and about 96 percent of hospitalizations due to rotavirus.

d. Immunization. ACIP recommends routine vaccination of infants with 3 doses of rotavirus vaccine administered orally at ages 2, 4, and 6 months. The first dose should be administered between ages 6–12 weeks. Subsequent doses should be administered

at 4–10-week intervals, and all 3 doses of vaccine should be administered by age 32 weeks. Vaccination should not be initiated for infants aged >12 weeks because of insufficient data on safety of the first dose of rotavirus vaccine in older infants. Vaccine should not be administered after age 32 weeks because of insufficient data on the safety and efficacy of rotavirus vaccine in infants after this age. For infants in whom the first dose of rotavirus vaccine is inadvertently administered off label at age >13 weeks, the rest of the rotavirus vaccination series should be completed as per the schedule because timing of the first dose should not affect the safety and efficacy of the second and third dose. Infants who have had rotavirus gastroenteritis before receiving the full course of rotavirus vaccinations should still initiate or complete the 3-dose schedule because the initial infection frequently provides only partial immunity.

Infants who are being breastfed can receive rotavirus vaccine. The efficacy of rotavirus vaccine is similar among breastfed and nonbreastfed infants. Like other vaccines, rotavirus vaccine can be administered to infants with transient, mild illnesses, and with or without low-grade fever.

e. Cautions. A child who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A child who has a severe (life threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your child has any severe allergies that you know of. Children who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes children who have diarrhea or vomiting. Check with your doctor if your child has any ongoing digestive problems. Check with your doctor if your child's immune system is weakened because of HIV/AIDS, or any other disease that affects the immune system-treatment with drugs such as long-term steroids-cancer, or cancer treatment with x-rays or drugs. Check with your doctor if your child recently had a blood transfusion or received any other blood product (such as immune globulin).

f. Adverse Events. Children are slightly (1-3%) more likely to have mild, temporary diarrhea or vomiting within 7 days after getting a dose of rotavirus vaccine than children who have not gotten the vaccine. A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of rotavirus vaccine causing serious harm, or death, is extremely small. Getting rotavirus vaccine is much safer than getting the disease.

g. DoD Policy. Follow ACIP recommendations and the product label.

3. References.

- a. Advisory Committee on Immunization Practices.
- b. CDC disease information. www.cdc.gov/nip/diseases/rota/rota-faqs.htm#disease
- c. MMWR, Recommendations and Reports, August 11, 2006, Vol. 55, No. RR-12. www.cdc.gov/mmwr/PDF/rr/rr5512.pdf

d. Multiple resources (e.g., package insert, Vaccine Information Statements, etc.) assembled by Military Vaccine Agency: <http://www.vaccines.mil/rotavirus>

LTC Stephen Ford/703-681-5101
Approved by COL Anderson